

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
October 12, 2004

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

**Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934**

For the month of October 2004

Commission File Number 0-16174

- 1 -

Teva Pharmaceutical Industries Limited

(Translation of registrant's name into English)

5 Basel Street, P.O. Box 3190

Petach Tikva 49131 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):
82- _____

Teva Pharmaceutical Industries Ltd.

Web Site: www.tevapharm.com

Contact: Dan Suesskind

Chief Financial Officer

Teva Pharmaceutical Industries Ltd.

(011) 972-2-589-2840

Bill Fletcher

President and CEO

Teva North America

FOR IMMEDIATE RELEASE (215) 591-8800

Dorit Meltzer

Director, Investor Relations

Teva Pharmaceutical Industries Ltd.

(011) 972-3-926-7554

TEVA ANNOUNCES FINAL APPROVAL AND LAUNCH OF GABAPENTIN CAPSULES

Jerusalem, Israel, October 8, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted final approval for the Company's ANDA for Gabapentin Capsules, 100 mg, 300 mg and

400 mg. Shipment of this product has commenced.

Gabapentin Capsules are the AB-rated generic equivalent of Pfizer's anticonvulsant, Neurontin[®] Capsules, which had annual sales of approximately \$1.7 billion for the twelve months ended June 2004.

Israel Makov, President and CEO of Teva commented, "We are pleased to have been able to work with Alharma in introducing this important generic product to U.S. consumers. Gabapentin leverages our world class capabilities in the production and development of bulk active pharmaceutical ingredients, our global manufacturing network, and our tremendous marketing reach."

Mr. Makov added, "Our overall business continues to perform strongly and the launch of Gabapentin will further strengthen it. We will provide investors with additional guidance when we report our financial results for the third quarter."

Teva's launch follows Alharma's introduction of Gabapentin Capsules earlier today. The companies will share Alharma's 180-day period of market exclusivity following Alharma's request that the FDA allow Teva to sell its product during the exclusivity period. This is pursuant to an agreement signed by the parties in April 2004. Under the terms of that agreement, Teva would make payments under certain conditions, based on its own sales of Gabapentin Capsules, to Alharma relating to the period of exclusivity.

In addition, Teva and Alharma have agreed to certain risk sharing arrangements relating to patent litigation regarding a Gabapentin launch. Patent litigation, which was initiated in 1998, is currently pending with Pfizer and a hearing on the pending summary judgment motions has been scheduled for November 18th and 19th, 2004 in the U.S. District Court for the District of New Jersey.

Teva has moved against Pfizer and its subsidiary Greenstone Ltd. to obtain immediate injunctive relief against the intrusion by Greenstone into the 180-day marketing exclusivity for Gabapentin Capsules.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, including its recent acquisition of Sicor Inc., the availability of product liability coverage in the current insurance market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind
Title: Chief Financial Officer

Date: October 08, 2004

